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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KOPPIKAR, VIVEK D	
ART UNIT	**PAPER NUMBER**
3626	

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/938,628	MORAND ET AL.	
	Examiner	Art Unit	
	Vivek D. Koppikar	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. Claims 1-68 have been examined in this application. This Final Office Action is in response to the "Amendment" and "Remarks" filed on June 8, 2006.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 4, 6-9, 11-14, 16, 21-24, 28-30, 33-36, 38, 42-44 and 66-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 5,991,729 in view of US Patent Number 6,368,797 to Schappert.

(A) As per claim 1, Barry teaches a method for identifying a research subject (Barry: Abstract), comprising:

obtaining medical data from a subject (Barry: Col. 4, Ln. 8-15);

associating an identifier for said subject with said medical data in at least a first database (Barry: Col. 4, Ln. 26-31);

associating the identifier for said subject with the name and contact information of said subject (Barry: Col. 4, Ln. 33-48);

extracting an identifier from the first database, wherein said identifier is associated with a subject matching the identified criteria (Barry: Col. 5, Ln. 53-62); and

matching the identifier from the first database with the name and contact information in order to identify the research subject (Barry: Col. 5, Ln. 53-62).

Barry does not teach the step of identifying criteria for selecting a research subject; however, this feature is well known in the art as evidenced by Schappert (Col. 12, Ln. 43-52). At the time of the invention it would have been obvious to one of ordinary skill in the art to have modified the method in Barry with the aforementioned feature from Schappert with the motivation of providing a powerful prognostic tool for the treatment of a disease as recited in Schappert (Col. 12, Ln. 27-33).

(B) As per claim 4, in the combined method of Barry in view of Schappert the method of claim 1 is repeated for each member (Barry: Col. 4, Ln. 32-52).

(C) As per claims 6-7, the combined method of Barry in view of Schappert teaches that the medical data comprise a medical history and a family history (Barry: Col. 4, Ln. 26-48).

(D) As per claim 8, in the combined method of Barry in view of Schappert the medical data comprise clinical chemistry test results (Barry: Col. 4, Ln. 7-12).

(E) As per claim 9, in the combined method of Barry in view of Schappert the medical data comprise pharmacogenomic or genomic data (Barry: Col. 4, Ln. 7-24).

(F) As per claim 11, in the combined method of Barry in view of Schappert the criteria includes medical history information (Barry: Col. 4, Ln. 26-48).

(G) As per claim 12, in the combined method of Barry in view of Schappert the criteria include family history information (Barry: Col. 4, Ln. 26-48).

(H) As per claim 13, in the combined method of Barry in view of Schappert the criteria include clinical chemistry test results (Barry: Col. 4, Ln. 7-12).

(I) As per claim 14, in the combined method of Barry in view of Schappert the criteria include pharmacogenomic or genomic information (Barry: Col. 4, Ln. 7-24).

(J) As per claim 16, in the combined method of Barry in view of Schappert the first database is a computerized database (Barry: Col. 4, Ln. 26-47).

(K) As per claims 21-23, in the combined method of Barry in view of Schappert the database is computerized, and the network is either an intranet or the Internet (Barry: Col. 4, Ln. 56-Col. 5, Ln. 6).

(L) As per claim 24, Barry teaches a method for identifying a research subject in a group of donors from at least one collection establishment, comprising:

a. obtaining a biological sample and medical data from a donor (Barry: Col. 4, Ln. 9-12);

b. associating an identifier for said donor with said biological sample and medical data in at least a first database (Barry: Col. 4, Ln. 32-48).

c. associating the identifier for said blood donor with the name and contact information of said donor (Barry: Col. 4, Ln. 32-48)

f. matching the identifier from the first database with the name and contact information in order to identify a research subject (Col. 4, Ln. 32-48).

Barry does not teach the step d. of identifying criteria for selecting a research subject nor does Barry teach the step e. of extracting an identifier from the first database, wherein said identifier is associated with a donor matching the identified criteria; however, this feature is well known in the art as evidenced by Schappert (Col. 12, Ln. 43-52). At the time of the invention it would have been obvious to one of ordinary skill in the art to have modified the method in Barry

with the aforementioned feature from Schappert with the motivation of providing a powerful prognostic tool for the treatment of a disease as recited in Schappert (Col. 12, Ln. 27-33).

(M) As per claim 28, in the combined method of Barry in view of Schappert the medical data comprises medical history data (Barry: Col. 4, Ln. 26-48).

(N) As per claim 29, in the combined method of Barry in view of Schappert the medical data comprise a family history (Barry: Col. 4, Ln. 26-48).

(O) As per claim 30, in the combined method of Barry in view of Schappert the medical data comprise clinical test results (Barry: Col. 4, Ln. 7-12).

(P) As per claim 33, in the combined method of Barry in view of Schappert the criteria include medical history information (Barry: Col. 4, Ln. 26-48).

(Q) As per claim 34, in the combined method of Barry in view of Schappert the criteria include family history information (Barry: Col. 4, Ln. 26-48).

(R) As per claim 35, in the combined method of Barry in view of Schappert the criteria include clinical test results (Barry: Col. 4, Ln. 9-12).

(S) As per claim 36, in the combined method of Barry in view of Schappert the criteria include pharacogenomic or genomic information (Barry: Col. 4, Ln. 7-24).

(T) As per claim 38, in the combined method of Barry in view of Schappert the first database is a computerized database (Barry: Col. 4, Ln. 26-29 and Ln. 48-52).

(U) As per claims 42-44, in the combined method of Barry in view of Schappert the database is computerized, and the network is either an intranet or the Internet (Barry: Col. 4, Ln. 56-Col. 5, Ln. 6).

(V) As per claim 66, the combined method of Barry in view of Schappert teaches the step of identifying the research subject according to claim 1 according to the selected criteria (Schappert: Col. 12, Ln. 43-52); and also teaches the step of contacting the research subject for recruiting the research subject for a clinical study (Barry: Col. 4, Ln. 26-47). The motivation for combining these two teaching is stated above in the paragraph setting forth the rejection of Claim 1.

(W) As per claim 67, the combined method of Barry in view of Schappert teaches the step of identifying the research subject according to claim 1 according to the selected criteria (Schappert: Col. 12, Ln. 43-52); and also teaches the step of contacting the research subject for recruiting the research subject for a clinical study (Barry: Col. 4, Ln. 26-47). The motivation for combining these two teaching is stated above in the paragraph setting forth the rejection of Claim 24.

4. Claims 2 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Schappert as applied to Claims 1 and 24, above, respectively.

(A) As per claims 2 and 25, the combined method of Barry in view of Schappert does not teach the step of obtaining informed consent from the subject, wherein the informed consent permits the medical data to be used to identify the subject as a potential research subject, however, the examiner takes Official Notice that this feature is well known in the field of patient and medical records. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have obtained informed consent from a patient before using that patient's medical records with the motivation of protecting the patient's right to privacy.

5. Claim 3 is rejected under 35 U.S.C. as being unpatentable over Barry in view of Schappert as applied to Claim 1, and in further view of US Patent Number 5,626,144 to Tacklind.

(A) As per claim 3, the combined method of Barry in view of Schappert does not teach or suggest that medical data are obtained from the subject and associated with the identifier for the subject in at least a first database longitudinally, however, this feature is well known in the art as evidenced by Tacklind (Col. 5, Ln. 55-63 and Col. 6, Ln. 5-13). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined method of Barry in view of Schappert with the aforementioned feature from Tacklind with the motivation of obtaining a means of pairing a patient with a remote sensor and a subscription pairing a device ID with a care provider, as recited in Tacklind (Col. 6, Ln. 5-14).

6. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of of US Patent Number 5,626,144 to Tacklind.

(A) As per claim 46, Barry teaches a plurality of biological samples collected from at least one subject (Barry: Abstract), wherein each sample is associated with an identifier linking said biological sample to at least one of medical data, genomic data, pharmacological data, and proteomic data in at least a first database (Barry: Col. 4, Ln. 7-47). Barry does not teach that the biological samples are collected and stored longitudinally, however, this feature is well known in the art as evidenced by Tacklind (Col. 5, Ln. 55-63 and Col. 6, Ln. 5-13). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the invention of Barry with the aforementioned feature from Tacklind with the motivation of

obtaining a means of pairing a patient with a remote sensor and a subscription pairing a device ID with a care provider, as recited in Tacklind (Col. 6, Ln. 5-14).

(B) As per claim 47, in the combined invention of Barry in view of Tacklind the samples are blood and blood cells (Barry: Col. 4, Ln. 7-12).

7. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Tacklind.

(A) As per claim 48, Barry teaches a plurality of biological samples collected from at least one donor (Barry: Abstract), wherein each sample is collected at a collection establishment and associated with an identifier linking the donor and the biological sample to at least one of medical data, genomic data, pharmacogenomic data, and proteomic data in at least a first database (Barry: Col. 4, Ln. 7-47). Barry does not teach that the biological samples are collected and stored longitudinally; however, this feature is well known in the art as evidenced by Tacklind (Col. 5, Ln. 55-63 and Col. 6, Ln. 5-13). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the invention of Barry with the aforementioned feature from Tacklind with the motivation of obtaining a means of pairing a patient with a remote sensor and a subscription pairing a device ID with a care provider, as recited in Tacklind (Col. 6, Ln. 5-14).

8. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Tacklind.

(A) As per claim 49, Barry teaches a method for creating a database (Barry: Abstract), the method comprising:

a. collecting a biological sample from at least one subject (Barry: Col. 4, Ln. 7-12);

b. collecting medical data from at least one subject (Barry: Col. 4, Ln. 7-12);

c. deriving proteomic information and genomic information from the sample (Barry: Col. 4, Ln. 22-26);

d. storing the sample in a location from which the sample can be recovered (Barry: Col. 4, Ln. 21-26);

e. associating the medical data, the proteomic information, and the genomic information with an identifier that can be used to locate the sample (Barry: Col. 4, Ln. 33-47).

Barry does not teach or suggest the step of f. of performing steps a to e on the same subject longitudinally; and wherein steps b to d may be performed in any order; however, this feature is well known in the art as evidenced by Tacklind (Col. 5, Ln. 55-63 and Col. 6, Ln. 5-13). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the method of Barry with the aforementioned feature from Tacklind with the motivation of obtaining a means of pairing a patient with a remote sensor and a subscription pairing a device ID with a care provider, as recited in Tacklind (Col. 6, Ln. 5-14).

(B) As per claim 50, in the combined method of Barry in view of Tacklind the steps a to f are performed on multiple subjects (patients) (Barry: Col. 5, Ln. 28-47).

(C) As per claim 51, in the combined method of Barry in view of Tacklind the biological sample is blood (Barry: Col. 4, Ln. 7-12).

(D) As per claim 52, in the combined method of Barry in view of Tacklind the samples are collected from at least one collection establishment (Barry: Col. 4, Ln. 7-12).

(E) As per claim 53, in the combined method of Barry in view of Tacklind the medical data comprises chemistry test formation (Barry: Col. 4, Ln. 16-26).

(F) As per claim 59, in the combined method of Barry in view of Tacklind the medical data comprises family histories from the subjects (Barry: Col. 4, Ln. 33-47).

(G) As per claim 60, in the combined method of Barry in view of Tacklind the medical data comprises demographic information from the subjects (Barry: Col. 4, Ln. 33-47).

(H) As per claim 61, in the combined method of Barry in view of Tacklind the medical data comprises at least one of the medical data, the genomic information, the proteomic information, and the location for the sample is associated with an identifier for the subject that can be used to retrieve the name and contact information for the subject (Barry: Col. 5, Ln. 19-27).

9. Claims 5, 27 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Schappert as applied to Claims 1 and 24, above, respectively, and in further view of US Patent Number 5,915,240 to Karpf.

(A) As per claims 5, 27 and 68, the combined method of Barry in view of Schappert does not teach or suggest that the subject (patient) is a deferred donor, however, this feature is well known in the art as evidenced by Karpf (Col. 14, Ln. 27-34). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the combined method of Barry in view of Schappert with the aforementioned feature from Karpf with the motivation of providing a means to providing descriptions of the patient, as recited in Karpf (Col. 14, Ln. 31-33).

10. Claims 9-10, 14-15, 31-32, and 36-37 are rejected as being unpatentable over Barry in view of Schappert as applied to Claims 1 and 24, above, respectively, and in further view of US Patent Number 6,730,477 to Sun.

(A) As per claims 9-10, 14-15, 31-32, and 36-37 the combined method of Barry in view of Schappert does not teach that the medical data comprises pharmacogenomic, genomic or proteomic data, however, this feature is well known in the art as evidenced by Sun (Col. 6, Ln. 61-Col. 7, Ln. 8 and Col. 7, Ln. 10-23 and Col. 8, Ln. 31-49). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have included these types of medical data in the combined method of Barry in view of Schappert with the motivation of obtaining an enhanced means of detecting, diagnosing and monitoring various diseases, as recited in Sun (Col. 3, Ln. 63-Col. 4, Ln. 4).

11. Claims 55-58 and 62-65 are rejected as being unpatentable over Barry in view of Tacklind, as applied to Claim 49, above and in further view of Sun.

(A) As per claims 55-58 and 62-65, the combined method of Barry in view of Tacklind does not teach that the medical data comprises pharmacogenomic, genomic or proteomic data as well as the other recited types of data in these claims, however, this feature is well known in the art as evidenced by Sun (Col. 6, Ln. 61-Col. 7, Ln. 8 and Col. 7, Ln. 10-23 and Col. 8, Ln. 31-49). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have included these types of medical data in the combined method of Barry in view of Schappert with the motivation of obtaining an enhanced means of detecting, diagnosing and monitoring various diseases, as recited in Sun (Col. 3, Ln. 63-Col. 4, Ln. 4).

12. Claims 17-20 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Schappert, as applied to Claims 1 and 24, above, respectively.

(A) As per claims 17-20 and 39-42, the combined method of Barry in view of Schappert does not teach or suggest a second computerized database stored on a separate computer and a

network firewall separating the first and second computers, however, the examiner take Official Notice that this is a feature well known in the field of informational technology and computer networks. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have included the above mentioned features with the motivation of providing a backup, archival data source so that vital patient data would not be destroyed if one of the computers was damaged.

Response to Arguments

13. Applicant's arguments ("Remarks") filed on June 8, 2006 have been fully considered but they are not persuasive. Applicants' arguments will be addressed in sequential order as they were presented in the "Remarks" section.

(1) Applicants argue against both the Barry and Schappert references because they claim that neither reference teaches identifying research subjects (or matching subjects with suitable research projects). However, the examiner would like to point out the step of "identifying a research subject" is a limitation which is part of the preamble in the claims and therefore this limitation has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

(2) Applicants next claim that the cited references (Barry and Schappert) fail to meet the claimed requirement of matching the patient's medical data with certain criteria for a

research project. However, the examiner would like to point out that Schappert does teach this feature in Column 12, Lines 39-52. In Schappert, a patient's health data is used to statistically assess a patient's likely outcome to therapy and also assess the patient's cure rate for a particular disease. Therefore, the examiner takes the position that in Schappert if a patient is found to be susceptible to a particular disease and it is also further assessed that the patient is likely to have a positive response to therapy then this patient is identified (using statistical criteria) as having a likelihood of responding positively to a therapy and therefore the patient is identified as a candidate for a particular therapy. The examiner takes the position that the term therapy includes those therapies that are in trial (clinical) stages as well as well-established therapies and that therefore the patients in Schappert that are given these therapies are research subjects. Thus, the above quoted passages of Schappert teach the step of identifying research subjects.

(3) Applicants argue that there is no motivation to combine Barry with Schappert, however the examiner would like to point out that proper motivation does in fact exist to combine these two teachings and this motivation has been clearly set forth in the rejection of claim 1, above.

(4) The applicants argue that the Tacklind reference does not require a physician or technician to input data or take a sample. However, the examiner would like to point out that the Tacklind reference is used to show that a particular type of processing and organizing data (compiling data longitudinally) is known in the art and the motivation for combining Tacklind with the combined teachings of Barry and Schappert is set forth in the rejections above. Moreover, the examiner would like to point out that Schappert teaches the step of a physician (or other healthcare professional) taking samples (from patients) (Schappert: Col. 12, Ln. 31-36).

(5) Applicants argue that Tacklind does not disclose steps (c)-(e) of claim 49. However, the examiner would like to point out that these steps are Barry in view of Schappert as set forth in the rejection of Claim 49, above (Schappert: Col. 3, Ln. 5-8).

(6) Applicants claim that the Karpf and Sun references and the Official Notice do not overcome the deficiencies of the Barry in view of Schappert rejection. However, the examiner would like to point out that the deficiencies of the 35 USC 103 rejection over Barry in view of Schappert have been addressed above in the other paragraphs of the "Response to Arguments" section. Karpf is used to show that the concept of a deferred donor is known in the art. Furthermore, proper motivation exists to combine the teachings Barry in view of Schappert with the teachings of Karpf as set forth above in the rejections of claims 5, 27 and 68. Sun is used to show that it is well known in the art that medical data comprises pharmacogenomic, genomic or proteomic data. Furthermore, proper motivation exists to combine the teachings Barry in view of Schappert with the teachings of Sun as set forth above in the rejections of claims 55-58 and 62-65. The examiner takes Official Notice with respect to the following feature: "a second computerized database stored on a separate computer and a network firewall separating the first and second computers. Furthermore, proper motivation exists to combine the teachings of Barry in view of Schappert with the Official Notice as set forth above in the rejections of Claims 17-20 and 39-42.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquire concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. The fax telephone numbers for this group are either (571) 273-8300 or (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

Vivek Koppikar

7/20/2006

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER